

# Electronic Cigarettes and the Public Health: A Public Workshop

**CENTER FOR TOBACCO PRODUCTS**  
The Marriott Inn and Conference Center  
University of Maryland University College  
Hyattsville, Maryland

**March 9-10, 2015**  
**Proposed Agenda**

**March 9**

**8:00 – 8:30 am**

*Welcome and Introduction of Center Director*  
Carolyn Dresler, MD, MPA  
Associate Director for Medical and Health Sciences  
Workshop Moderator  
FDA Center for Tobacco Products

*Opening Remarks*  
Mitchell Zeller, JD  
Director  
FDA Center for Tobacco Products

*Overview and Procedures*  
Elizabeth Durmowicz, MD  
Medical Team Lead  
FDA Center for Tobacco Products

**8:30 – 9:40 am**

## **Exposures in Users – Inhalational Toxicology Considerations**

*Potential Inhalation Toxicology Evaluations of E-Cigarettes*  
Mark Higuchi, MSc, PhD  
United States Environmental Protection Agency

*What's in the Toolbox? Nonclinical Models for the Evaluation of Electronic Cigarettes and Other Alternative Tobacco Products*  
Jacob McDonald, PhD  
Lovelace Respiratory Research Institute

*Particle Size Distribution and Associated Toxicologic Implications of Electronic Cigarette Aerosol*  
Courtney A. Granville, PhD, MSPH  
Battelle Public Health Center for Tobacco Research

*Validated Computational Fluid-Particle Dynamics Simulations for Toxicological Considerations and Health-effect Evaluations of Inhaled Multicomponent Droplet-Vapor Mixtures from Electronic Cigarettes*  
Yu Feng, PhD  
North Carolina State University

## **Clarifying Questions**

**9:40 – 10:35 am**

## **Flavorings, Propylene Glycol, and Glycerin**

*Considerations Regarding the Impact of Flavorings*  
Jessica Barrington-Trimis, PhD  
University of Southern California

*Toxicology of Inhaled Diacetyl and 2,3-Pentanedione: Chemicals Implicated in Flavorings-Related Lung Disease*

Ann Hubbs, DVM, PhD  
National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention

*E-cigarette Flavor Product Stewardship*  
Sandra Costigan, PhD, MSc  
Nicoventures

*Review of Propylene Glycol and Glycerin Inhalation Studies*  
Michael Oldham, PhD  
Altria Client Services Inc.

### **Clarifying Questions**

**10:35 – 10:50 am**      **Break**

**10:50 – 11:20 am**      **Toxicology Panel**

Panelists:

- Neal Benowitz, MD (University of California, San Francisco)
- Charles Garner, PhD (RAI Services Company)
- Donald Graff, PharmD (Celerion)
- Courtney A. Granville, PhD, MSPH (Batelle Public Health Center for Tobacco Research)
- Mark Higuchi, MSc, PhD (US Environmental Protection Agency)
- Jacob McDonald, PhD (Lovelace Respiratory Research Institute)
- Willie McKinney, PhD (Altria Client Services, Inc.)

**11:20 – 11:40 am**      **E- Cigarette Addiction – Introduction and Overview**

*Introduction*  
Megan J. Schroeder, PhD  
FDA Center for Tobacco Products

*The Clinical and Behavioral Pharmacology Associated with E-cigarettes: An Overview*  
Peter Shields, MD  
James Cancer Hospital and Comprehensive Cancer Center, The Ohio State University

**11:40 – 12:15 pm**      **E-Cigarette Topography**

*E-cigarette Consumption and Puffing Topography Data*  
Sudhanshu Patwardhan, MBBS, MS, MBA  
Nicoventures, British American Tobacco

*E-cigarette use Topography: Variation among Users in Realistic Conditions; Changes According to Power Levels; Association with Nicotine Absorption*  
Konstantinos Farsalinos, MD  
University of Patras, Greece

### **Clarifying Questions**

**12:15 – 1:15 pm**      **Lunch**

**1:15 – 2:25 pm**      **Nicotine Exposure and Pharmacokinetics**

*Nicotine Pharmacokinetics and Systemic Uptake from Different E-cigarette Devices*  
Gideon St.Helen, PhD  
University of California, San Francisco

*Exposure to Nicotine and Toxicants among Exclusive Users of Electronic Cigarettes and Dual Users of Electronic and Tobacco Cigarettes*  
Maciej Goniewicz, PhD, PharmD  
Roswell Park Cancer Institute

*Electronic Cigarettes: Nicotine Delivery and Puff Topography*  
Thomas Eissenberg, PhD  
Virginia Commonwealth University

*E-cigarette Nicotine Pharmacokinetics and Impact on Urge-to-Smoke Symptoms, Cardiovascular Function and Short-Term Tolerability*  
X. Sherwin Yan, PhD, MD  
Lorillard Tobacco Company

### **Clarifying Questions**

**2:25 – 3:00 pm**

### **Abuse Liability**

*Animal Models for Assessing the Relative Abuse Liability of Electronic Cigarettes*  
Andrew Harris, PhD  
University of Minnesota

*Using Behavioral Economics to Assess the Abuse Liability of E-cigarettes*  
Matthew W. Johnson, PhD  
Johns Hopkins University

### **Clarifying Questions**

**3:00 – 3:15 pm**

### **Break**

**3:15 – 4:30 pm**

### **Pharmacodynamics and Subjective Effects**

*Evaluation of an Electronic Vapour Product: Nicotine Pharmacokinetics, Safety and Efficacy*  
Tanvir Walele, BSc, MSc, ERT  
Fontem Ventures

*Subjective Effects: Measurement Issues*  
Richard O'Connor, PhD  
Roswell Park Cancer Institute

*Experienced "Tank-Type" ENDS Users: Usage Patterns, Pharmacokinetics, and Puff Topography*  
Mitchell Nides, PhD  
Los Angeles Clinical Trials

*Assessing Dependence*  
Jonathan Foulds, PhD  
Pennsylvania State University

### **Clarifying Questions**

**4:30 – 5:00 pm**

### **Addiction Panel**

Panelists:

- Thomas Eissenberg, PhD (Virginia Commonwealth University)
- Konstantinos Farsalinos, MD (University of Patras, Greece)
- Jonathan Foulds, PhD (Pennsylvania State University)
- Jack Henningfield, PhD (PinneyAssociates)
- Michael Hufford, PhD (e-Nicotine Technology)

- *Peter Shields, MD (James Cancer Hospital and Comprehensive Cancer Center, The Ohio State University)*
- *Linc Williams (American E-liquid Manufacturing Standards Association)*

**End of Workshop – Day 1**

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**Proposed Agenda**

**March 10**

**8:00 – 8:05 am**

*Welcome*  
Jeannie Limpert, MD  
Medical Officer  
FDA Center for Tobacco Products

**8:05 – 9:35 am**

**Public Comment Session**

**9:35 – 9:50 am**

***Break***

**9:50 – 12:00 pm**

**Health Effects in Users**

*Health Effects of E-Cigarettes: An Overview*  
M. Brad Drummond, MD, MHS  
Johns Hopkins University School of Medicine

*ENDS and the Oral Microbiome*  
Purnima Kumar DDS, PhD  
The Ohio State University

*Cardiovascular Effects and Potential Cardiovascular Disease Risk Associated with Electronic Cigarette Use*  
Aruni Bhatnagar, PhD  
University of Louisville

*Possible Health Effects of E-Cigarettes*  
William Bailey, MD  
University of Alabama at Birmingham

***Clarifying Questions***

*Potential Risks and Benefits of Electronic Cigarette Use During Pregnancy*  
Cheryl Oncken, MD, MPH  
University of Connecticut Health Center

*Electronic Cigarette Use in Pregnancy: Potential Effects on Fetal Health and Development*  
Melissa Suter, PhD  
Baylor College of Medicine

*Nicotine Addiction and E-cigarettes*  
Joseph DiFranza, MD  
University of Massachusetts Medical School

***Clarifying Questions***

**12:00 – 1:00 pm**

***Lunch***

**1:00 – 2:00 pm**

**Health Effects in Users (continued)**

*Toxicant and Carcinogen Metabolites in the Urine of e-Cigarette Users*  
Stephen Hecht, PhD  
University of Minnesota

*E-cigarettes for Smoking Cessation: Findings from the Cochrane Review*  
Chris Bullen, MPH, PhD  
The University of Auckland

*Pulmonary Safety Testing for Inhalational Drug Products*  
Theresa Michele, MD  
FDA Center for Drug Evaluation and Research

**Clarifying Questions**

**2:00 – 2:30 pm**

**Health Effects Panel**

Panelists:

- William Bailey, MD (University of Alabama at Birmingham)
- Neal Benowitz, MD (University of California, San Francisco)
- M. Brad Drummond, MD, MHS (Johns Hopkins School of Medicine)
- Stephen Hecht, PhD (University of Minnesota)
- Cheryl Oncken, MD, MPH (University of Connecticut Health Center)

**2:30 – 2:45 pm**

**Break**

**2:45 – 3:45 pm**

**Adverse Experiences and Risk Assessment**

*Electronic Cigarettes: Adverse Experiences Reported to FDA CTP*  
Jeannie Limpert, MD  
FDA Center for Tobacco Products

*Role of Human Factors Engineering in Medical Product Development*  
Edmond W. Israelski, PhD  
AbbVie Inc.

*Product Labeling and Consumer Labeling Comprehension*  
James P. Stansbury, PhD, MPH  
FDA Center for Drug Evaluation and Research

**Clarifying Questions**

**End of Workshop – Day 2**